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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/019,816 | 03/27/2002 | Michael Valentine Agrez | ADAM-046XX | 9944 |

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WEINGARTEN, SCHURGIN, GAGNEBIN & LEBOVICI LLP
TEN POST OFFICE SQUARE
BOSTON, MA 02109

| EXAMINER | |
|---|---|
| CANELLA, KAREN A | |
| ART UNIT | PAPER NUMBER |
| 1643 | |
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| 06/09/2010 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/019,816 | AGREZ ET AL. | |
| | Examiner | Art Unit | |
| | Karen A. Canella | 1643 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *217-219,225,238 and 277* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *217-219, 225, 238 and 277* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

Claim 221 has been canceled. Claims 217-219 and 277 have been amended. Claims 217-219, 225, 238 and 277 are pending and under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 277 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A)Claim 277 has been amended to recite "up to 25 amino acids" which includes a polypeptide as small as 2 amino acids to 24 amino acids. Applicant refers to page 49 for support for this amendment. This has been considered but not found persuasive. Page 49 states that the polypeptides will preferable be between 5 and 25 amino acids in length which does not support the instant amendment of "up to" 25 amino acids.

Claims 217-219, 221, 225, 238, 277, 283 and 285-287 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inhibiting the growth of a cancer cell comprising providing a binding domain comprising SEQ ID NO:2-5, 22 or 23, , does not reasonably provide enablement for a method for inhibiting the growth of a cancer cell comprising providing portions of SEQ ID NO:2-5, 22 or 23. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims..

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of

direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(A) Claims 217, 218, 221, 225, 238 are drawn to a method reliant on a genus of polypeptides that encompass amino acid sequences of the binding domains of SEQ ID NO:2, 22 and 23, essential for binding to a map kinase having a linker sequence which is non-essential fro binding of the MAP kinase which links opposite end regions of the binding domain together, and claims 277, 283, 286 and 287 are drawn to a method reliant on a genus of polypeptides that encompass deletion of amino acid sequences non-essential for binding to the MAP kinase from the binding domain of SEQ ID NO:2, 22 or 23.

The instant specification teaches that SEQ ID NO:2, 22 and 23 bind to the MAP kinase of Erk2. The specification teaches that the polypeptide will comprise the binding domain of the integrin, or sufficient core amino acid sequence of the binding domain to enable binding of the polypeptide with the MAP kinase (page 13, lines 1-3). The instant specification teaches RSKAKWQTGTNPLYR (SEQ ID NO:2) as a preferred embodiment, along with RSKAKNPLYR (SEQ ID NO:3) or one or both of RSKAK (SEQ ID NO:4) and NPLYR (SEQ ID NO:5). It appears that SEQ ID NO:3 represents SEQ ID NO:2 with a deletion of the amino acids WQTGT, and that SEQ ID NO:4 and 5 are the amino terminal and carboxyl terminal sequences of SEQ ID NO:2. Given that SEQ ID NO:2 is only 15 amino acids in length and the 5 amino terminal amino acids and 5 carboxyl terminal amino acids can bind to MAP kinase without the WQTGT sequence, one of skill in the art would be forced into undue experimentation without reasonable expectation of success to find further core fragments of SEQ ID NO:2 that can specifically bind to Erk2 because SEQ ID NO:4 and 5 are already down to 5 amino acids. The specification fails to teach other smaller fragments of a integrin binding domain that can function independent of the binding domain to specifically bind Erk2. The specification states that binding of Erk2 to the beta-5 and beta-3 peptides was also found (page 92, lines 10-11) but fails to state if the corresponding amino terminal or carboxyl terminal regions in the beta-5 and beta-3 peptides would function out of context of the binding domain to bind to Erk2. The specification teaches that the results of binding indicate a hierarchy of binding of Erk2 to integrin subunits (page 92, lines 12-14) but fails to state what the order is within the hierarchy. Further, Figure 34 is stated to represent the binding of erk2 to the instant SEQ ID

NO:2 (beta-6), and corresponding regions of the cytoplasmic domains of beta-3 and beta-5, which do not bind to Erk2 to the same extent as RSKAKWQTGTNPLYR (binding region of beta-6). Thus, there is doubt that sub-regions of the binding domains from beta-3 and Beta-5 would necessarily retain specific binding to Erk2 because the entirety of the binding region does not bind as strongly to Erk2 as RSKAKWQTGTNPLYR (binding region of beta-6). Therefore one of skill in the art would be subject to undue experimentation without reasonable expectation of success in order to practice the claimed invention with fragments of beta-6 that were not SEQ ID NO:4 and 5, fusion protein of SEQ ID NO:3, or subunits of the bindings domain of beta-3 and beta-5, linked together or not, with amino acids non-essential for binding to ERK2.

Applicant argues that the amended claims include the binding domain to be selected from the group consisting of SEQ ID NO:2, 22 or 23, wherein the binding domains either include or exclude the liker sequence. This has been considered but not found persuasive. Claim 217 as written is drawn to a linear polypeptide comprising an amino acid sequence "defining" a binding domain which includes or exclude the linker sequence. It appears from the context of the claim if a fragment of the amino acid sequence which "defines" the binding domain is to be connected to another fragment of the binding domain by the linker sequence, or upon exclusion of the linker sequence, the binding domain amino acids remain continuous. This he portion of the claim including the linker sequence is drawn to a non-contiguous binding domain of SEQ ID NO:2, 22 or 23. Applicants arguments regarding the teachings of the specification at page 26, lines 11-26 regarding the deletion of amigo acids from the binding domain while retaining binding activity is not persuasive because the cited text is general contemplation rather than specific teachings.

All other rejections and objections as set forth in the prior Office action are withdrawn in light of applicant's arguments.

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/
Primary Examiner, Art Unit 1643